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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,393

01/31/2006

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,393	<b>Applicant(s)</b> JIANG ET AL.	
	<b>Examiner</b> Elli Peselev	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-105, 107-146 and 148-158 is/are pending in the application.  
4a) Of the above claim(s) 31-35, 66-91 and 140-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30, 36-49, 52-63, 92-139 and 143-157 is/are rejected.
- 7) ☒ Claim(s) 50, 51, 64, 65 and 158 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

The Non-Final Office Action of December 5, 2008 is hereby withdrawn and the Non-Final Rejection is set herein below.

Applicant's election with traverse of Group V in the reply filed on 8/28/2008 is acknowledged. The traversal is on the ground(s) that compounds encompassed by Groups I, V, IV and VI overlap. This has been found persuasive. Therefore the restriction between Groups I, V, IV and VI is hereby withdrawn and said groups are rejoined. With respect to Groups II, III, VII, VIII, IX, X and XI, the restriction requirement is still deemed to be proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-35, 66-91 and 140-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/28/2008.

Claims 1-30, 36-49, 52-63, 92-105, 107-139 and 143-146, 148-157 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would

not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The compound claims encompass an immense number of species.

The method claims 107-139 are directed to a method of protecting a subject against a virus, microbial infection, parasite or cancer.

(B) The level of predictability in the art.

It is well known in the pharmaceutical art that changes in structural formula of a compound can lead to major in its activity.

(C) The amount of direction provided by the inventor.

The specification discloses 14 specific compounds having closely related structural formulas. No evidence is provided showing that the discloses compounds are effective in protecting against viral, microbial and parasitic infections is provided.

Fig. 24 shows the activity of BC1-041 and BC1-049 compounds for cytokine secretion by BALB/c spleen cells.

Fig. 25 shows proliferation of Ba1b/c WT splenocytes in response to compounds 038, 040, 041, 049 and anti-CD3.

It also shows IFN-gamma production in response to compounds 038, 040, 041, 049, 050 and anti-CD3.

However, there is no known correlation between the activity shown in Figures and the protection against viral, microbial and parasitic infections and cancer.

The disclosure of specific compounds and their activity shown in Figures in clearly not commensurate with the broad scope of the claimed invention.

(D) The existence of working examples.

The evidence is limited to shoeing the activity of a limited structurally closely related compounds.

(E) The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Claims 1-30, 36-48, 52-61, 63, 92-139 and 143-158 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprises" (all occurrences) renders the claims indefinite in that it leaves the structural formula of the claimed compound open-ended i.e. the metes and bounds of the claimed invention cannot be determined.

Claim 46 is indefinite in that variables F, Z and Z' have not been defined.

There is no antecedent basis for the terminology "as previously defined" (claims 63 and 74).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Behar et al (US 2002/0115424).

Behar et al disclose the claimed glycosylceramides analogues (pages 19-30).

Claims 50, 51, 64, 65 and 158 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Elli peselev

/Elli Peselev/

Primary Examiner, Art Unit 1623